UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,192	03/01/2002	David W. Morris	PP23696.0001/20366-035001	7201

55255 7590 02/05/2010

Novartis Vaccines and Diagnostics, Inc.
Corporate Intellectual Property
P.O. BOX 8097
EMERYVILLE, CA 94662-8097

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
02/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,192	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,21,22 and 24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *11, 21, 22 and 24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Arguments

1. Claims 11, 21, 22 and 24-39 are pending.

Claims 11, 24, 34 and 39 have been amended.

Claims 11, 21, 22 and 24-39 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The rejection of claims 11 and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Sikut et al. (Biochemical and Biophysical Research Communications 238: 612-616, 1997/ IDS reference AG submitted November 25, 2008) is withdrawn in light of Applicants' amendments to claims 11 and 22.

Claim Rejections - 35 USC § 103

4. The rejection of claims 11 and 21 under 35 U.S.C. 103(a) as being unpatentable over Sikut et al. (Biochemical and Biophysical Research Communications 238: 612-616, 1997/ IDS reference AG submitted November 25, 2008), and further in view of U.S. Patent Application Publication number

2004/0038207 A1 (filed September 14, 2001) is withdrawn in light of Applicants' amendments.

5. The rejection of claims 11 and 21 under 35 U.S.C. 103(a) as being unpatentable over Sikut et al. (Int. J. Cancer 82(1): 52-58, July 2, 1999/ IDS reference AH submitted November 25, 2008), and further in view of U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001) is withdrawn in light of Applicants' amendments.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The rejection of claim 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants assert the Examiner has set forth a rejection that is not proper because she relies upon case law that is not parallel to the claimed invention, see Remarks submitted November 18, 2009, page 6. Applicants further arguments noting the requirements for written description and asserting their "...specification provides sufficient written description for the pending claims",

see page 7 of the Remarks. Applicants also attempt to further arguments asserting Example 14 listed in the Office's Written Description Guidelines are comparable to the claimed invention. These points of view and arguments have been carefully considered, but fail to persuade.

Applicants are reminded foremost that their claim reads on a single nucleotide sequence which shares at least 98% sequence identity to *a single sequence* of SEQ ID NO: 1175. Example 14 of the Guidelines reads on "Antibodies to a Genus of Proteins" and the Examiner is not sure of the parallel to the claimed invention, nonetheless sequence identity is based on SEQ ID NO: 3 in its entirety and not a single sequence.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Applicants may obviate the instant rejection with the deletion of the phrase "a sequence of" on line 4, see the claim language of claim 11, lines 3 and 4.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The rejection of claims 22 and 24-38 under 35 U.S.C. 102(b) as being anticipated by Sikut et al. (Biochemical and Biophysical Research Communications 238: 612-616, 1997/ IDS reference AG submitted November 25, 2008) is maintained.

Applicants simply assert they do not agree that Sikut anticipates their claims due to claim amendments, see page 8 of Remarks submitted November 18, 2009. This argument has been carefully reviewed and considered, but found unpersuasive.

Independent claims 22 and 34 continue to read on colon samples, as well as claim 34 requires a nucleotide to have at least 98% sequence identity to a single nucleotide of SEQ ID NO: 1175, see pending 112, 1st written description rejection and claim language of claim 34, section a. Sikut continues to disclose a method of detecting CD43 (also art known as leukosialin and sialophorin) in colon adenoma and carcinoma tissues utilizing Western blot analysis and immunohistochemistry, see abstract; and page 613, Table 1.

Furthermore, the Examiner notes at the conclusion of the arguments regarding 35 U.S.C. 102 that the Action fails to address the expressly recited features of several of the pending dependent claims, see Remarks, page 10. Applicants' dependent claims merely state wherein clauses that do not impart novelty. The dependent claims merely state the results of the active step, detecting either sialophorin or SEQ ID NO: 1175 adding nothing to the patentability or substance of the claim, hence not given weight. It simply expresses the intended result of the positively recited process steps. Consequently, the rejection is maintained for the reasons of record and cited herein.

10. The rejection of claims 22, 24-29 and 31-38 under 35 U.S.C. 102(b) as being anticipated by Sikut et al. (Int. J. Cancer 82(1): 52-58, July 2, 1999/ IDS reference AH submitted November 25, 2008) is maintained.

Applicants simply assert they do not agree that Sikut anticipates their claims due to claim amendments, see page 8 of Remarks submitted November 18, 2009. This argument has been carefully reviewed and considered, but found unpersuasive.

Independent claims 22 and 34 continue to read on colon samples, as well as claim 34 requires a single nucleotide to have at least 98% sequence identity to a single nucleotide of SEQ ID NO: 1175, see pending 112, 1st written description rejection and claim language of claim 34, section a. Sikut continues

to disclose a method of detecting CD43 (also art known as leukosialin and sialophorin) in colon adenoma and adenocarcinoma tissues utilizing Western blot analysis, immunoprecipitation and immuno-histochemistry, see abstract. The rejection is maintained for the reasons of record and cited herein.

11. The rejection of claims 22, 24-29 and 31-38 under 35 U.S.C. 102(b) as being anticipated by Topalovski et al. (Arch. Pathol. Lab Med. 123: 1208-1218, December 1999) is maintained.

Applicants submit Topalovski does disclose CD43 (also art known as leukosialin and sialophorin) as a maker used to immunophenotype breast lymphomas, however it is used along with a host of other markers, see Remarks, page 8, last paragraph. Applicants conclude arguments setting forth the principles required for a proper 102 rejection, see Remarks, paragraph bridging pages 8 and 9. Applicants' arguments and points of view have been carefully considered, but found unpersuasive.

Topalovski's disclosure of additional markers that can be used to identify and diagnose lymphomas does not preclude the instant rejection. Topalovski continues to disclose a method of detecting CD43 in biopsies from primary breast lymphoma and secondary breast lymphoma, see page 1208, Results and Materials...sections. Topalovski reads on Applicants' claims, in which differential expression of sialophorin is detected. The rejection is maintained for the reasons of record and cited herein.

12. The rejection of claims 22, 24-29 and 31-38 under 35 U.S.C. 102(b) as being anticipated by Aguilera et al. (Mod. Pathol. 13(6): 599-604, 2000) is maintained.

Applicants assert "...CD43 merely as a T-cell marker" and one of several markers used to identify cell type, see page 9 of the Remarks. Applicants aver the Examiner correctly points out that the reference does not teach all the elements of the claimed invention. Applicants conclude arguments setting forth the principles required for a proper 102 rejection, see Remarks, paragraph bridging pages 9 and 10. Applicants' arguments and points of view have been carefully considered, but found unpersuasive.

It is art known that CD43 is also known as sialophorin, the same as that in Applicants' claims. The mere fact that Aguilera discloses the identification of other candidate tumor markers in breast lymphomas does not teach away from Aguilera's disclosure. Aguilera continues to disclose detecting CD43 breast cancers utilizing immunohistochemistry, see page 299, Immunohistochemistry section; Results section beginning on page 600, particularly Cases 1 and 3; page 604, Table 3. The rejection is maintained for the reasons of record and cited herein.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The rejection of claims 22 and 24-39 under 35 U.S.C. 103(a) as being unpatentable over Sikut et al. (Biochemical and Biophysical Research Communications 238: 612-616, 1997/ IDS reference AG submitted November 25, 2008), and further in view of Orntoft/ U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001) is maintained.

Applicants simply assert they do not agree that Sikut anticipates their claims due to claim amendments, see page 10 of Remarks submitted November 18, 2009. This argument has been carefully reviewed and considered, but found unpersuasive.

For the reasons presented in the pending 102(b) rejection, the instant rejection is maintained, see section 8 of this Action.

15. The rejection of claims 22 and 24-39 under 35 U.S.C. 103(a) as being unpatentable over Sikut et al. (Int. J. Cancer 82(1): 52-58, July 2, 1999/ IDS reference AH submitted November 25, 2008), and further in view of Orntoft/ U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001) is maintained.

Applicants simply assert they do not agree that Sikut anticipates their claims due to claim amendments, see bridging paragraphs of pages 10 and 11 of Remarks submitted November 18, 2009. This argument has been carefully reviewed and considered, but found unpersuasive.

For the reasons presented in the pending 102(b) rejection, the instant rejection is maintained, see section 8 of this Action.

16. The rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. 103(a) as being unpatentable over Aguilera et al. (Mod. Pathol. 13(6): 599-604, 2000), and further in view of Orntoft/ U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001) is maintained.

Applicants aver the instant reference does not teach detecting CD43 breast cancers utilizing immunohistochemistry as listed by the Examiner in the pending 102(b) rejection. Applicants assert "...CD43 merely as a T-cell marker" and one of several markers used to identify cell type, see page 11 of the Remarks. Applicants' arguments and points of view have been carefully considered, but found unpersuasive.

The mere fact that Aguilera discloses the identification of other candidate tumor markers in breast lymphomas does not teach away from Aguilera's disclosure. Clearly on page 601 of Aguilera, 2nd column it is written "Immunohistochemical studies showed that the malignant cells were immunoreactive with ...CD43...". This reference is not deficient and it still would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of both documents in order to effectively diagnose breast cancer using the methodologies cited therein using the hybridization criteria set forth in the claim. For the reasons presented herein and previous, the instant rejection is maintained.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the

advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
26 January 2010

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643